

(19) World Intellectual Property  
Organization  
International Bureau



(43) International Publication Date  
16 June 2005 (16.06.2005)

PCT

(10) International Publication Number  
**WO 2005/053547 A2**

(51) International Patent Classification: **A61B 17/12**

P.O. Box 489, Bloomington, IN 47402 (US). **COOK BIOTECH INCORPORATED** [US/US]; 3055 Kent Avenue, West Lafayette, IN 47906 (US).

(21) International Application Number:  
PCT/US2004/039840

(72) Inventors; and

(22) International Filing Date:  
29 November 2004 (29.11.2004)

(75) Inventors/Applicants (for US only): **PAVCHNIK**, Dusan [US/US]; 7676 S.W. Skyhar Drive, Portland, OR 97223 (US). **KAUFMAN**, John, A. [US/US]; 14210 Amberwood Circle, Lake Oswego, OR 97039 (US). **OSBORNE**, Thomas [US/US]; 9480 S. Pointe LaSalle Drive, Bloomington, IN 47401 (US). **BATES**, Brian [US/US]; 3718 Exeter Lane, Bloomington, IN 47401 (US). **PATEL**, Umesh [US/US]; 1135 Kingswood Road South, West Lafayette, IN 47906 (US). **FETTE**, Clay, D. [US/US]; 1503 Austin Dr., Lebanon, IN 46052 (US). **CHIN**, Likang [US/US]; 2280 South Overlook Road, Cleveland Heights, OH 44106 (US). **MC ALEXANDER**, Chad, S. [US/US]; 118 S. 9th St., #3, Lafayette, IN 47901 (US). **SHAH**, Bhavin [IN/US]; 2550 Yeager Road, #8-6, West Lafayette, IN 47906 (US).

(25) Filing Language: English

(26) Publication Language: English

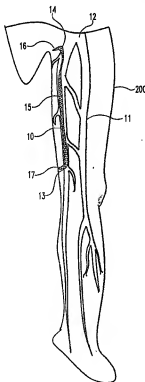
(30) Priority Data:  
60/525,793 28 November 2003 (28.11.2003) US  
60/557,248 29 March 2004 (29.03.2004) US

(71) Applicants (for all designated States except US): **COOK INCORPORATED** [US/US]; 925 South Curry Pike,

[Continued on next page]

(54) Title: **VASCULAR OCCLUSION METHODS, SYSTEMS AND DEVICES**

(57) Abstract: Described are devices, methods and systems useful for achieving occlusion of vascular vessels. Percutaneous procedures are used to occlude and obliterate the greater saphenous vein, for example in the treatment of varicose vein condition caused by venous reflux. Certain embodiments encompass the deployment of one or more vascular occlusion devices via a through-and-through percutaneous procedure that leaves the vascular occlusion device or devices in a through-and-through condition.



WO 2005/053547 A2



(74) Agents: GANDY, Kenneth, A. et al.; Woodard, Emhardt, Moriarty, Mcnett & Henry LLP, Bank One Center/Tower, Suite 3700, 111 Monument Circle, Indianapolis, IN 46204 (US).

(81) Designated States (unless otherwise indicated, for every kind of national protection available): AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BW, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NA, NI, NO, NZ, OM, PG, PH, PL, PT, RO, RU, SC, SD, SE, SG, SK, SL, SY, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, YU, ZA, ZM, ZW.

(84) Designated States (unless otherwise indicated, for every kind of regional protection available): ARIPO (BW, GH, GM, KE, LS, MW, MZ, NA, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European (AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HU, IE, IS, IT, LU, MC, NL, PL, PT, RO, SE, SI, SK, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

**Published:**

— without international search report and to be republished upon receipt of that report

For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

**VASCULAR OCCLUSION METHODS, SYSTEMS AND DEVICES**

5

**STATEMENT OF RELATED APPLICATIONS**

This application claims the benefit of priority of U.S. Provisional Patent Application Serial No. 60/525,793 filed November 28, 2003 and U.S. Provisional  
10 Patent Application Serial No. 60/557,248 filed March 29, 2004, all of which are incorporated herein by reference.

15

**BACKGROUND**

The present invention resides generally in the field of devices and methods useful for the occlusion of vascular vessels, and in a particular aspect relates to the occlusion of the greater or lessor saphenous  
20 vein to treat complications, such as varicose vein condition, resultant of venous reflux.

As further background, the human venous system generally includes a superficial venous system and a  
25 deep venous system, with perforating veins connecting the two systems. In human legs, the superficial system includes the great saphenous vein and the short saphenous vein. The deep system of the legs includes the anterior and posterior tibial veins which join to  
30 form the popliteal vein, which becomes the femoral vein when united with the short saphenous vein.

Such venous systems are designed to carry blood back to the heart. To facilitate this function, the

venous systems contain one-way valves, which are typically bicuspid. The failure of venous valves leads to retrograde flow or reflux within the venous system. This can result in various venous diseases which

5 include varicose veins and chronic venous insufficiency. In the varicose vein condition, the superficial veins of the leg become dilated and tortuous and can result in discoloration, pain and ulceration. The varicose vein condition commonly

10 involves the incompetence of one or more venous valves which allow reflux of blood from the deep venous system to the superficial venous system or reflux within the superficial system. In many cases, blood from the deep vein system refluxes back down the greater saphenous

15 vein leading to varicosity within superficial veins below the greater saphenous vein.

Surgical stripping of the greater saphenous vein is an extensively practiced technique for treating the

20 varicose vein condition. In this technique, an incision is made in the groin to expose the sapheno-femoral junction, where the great saphenous vein and its branches are ligated. The distal portion of the greater saphenous vein has been exposed by incision

25 interior to the medial malleolus, and a stripping device is introduced to exit from the proximal saphenous vein. After holding the leg vertical for a time to empty the venous tree, the vein is stripped from the ankle to the groin. In cases wherein the

30 small saphenous vein is also incompetent, it is stripped at the same time from an incision posterior to the lateral malleolus to the popliteal space. After

stripping, the leg is held vertically for a time to permit vessel ends to retract, constrict and clot. The stripping procedure is commonly followed by the removal of collateral veins working through small incisions using an avulsion-extraction technique.

More recently, techniques have been developed to try to avoid the invasive stripping procedure and its associated complications. For example, techniques and devices have been developed to treat the varicose vein condition with radiofrequency (RF) energy. In these techniques a catheter having an electrode tip is used to deliver RF energy within the vein to be treated. The RF energy causes localized heating and shrinkage of the venous tissue. The electrodes can be drawn through or repositioned within the vein to treat different sections or segments of the vein. For additional information on RF treatments and devices, reference can be made for example to US Patent Nos. 6,200,312, 6,179,832, 6,165,172, 6,152,899, 6,071,277, 6,036,687, 6,033,398, 6,014,589, and 5,609,598.

Another technique which has been developed is the endovenous laser technique. This technique is typically performed under local or regional anesthesia. A bare laser fiber is inserted into the diseased vein and delivers laser light in a pulsed fashion to heat the vein to cause damage and constriction. See, e.g., Gorisch et al., "Heat Induced Contraction of Blood Vessels", Laser Surgery Medicine 2(1), 1-13(1982). Other techniques for treating the varicose vein condition includes sclerotherapy, in which a sclerosing

solution is injected into the vein to damage the interior of the vein, followed by compression wrapping to facilitate permanent closure of the damaged vein. Phlebectomy is a procedure also utilized to treat  
5 varicose veins, typically medium sized and larger veins. In this procedure, small stab incisions are made in the skin and a tool is used to hook and pull the vein out through the incision.

10 In view of this background, the need remains for improved and alternative techniques, devices and systems for affecting the venous system to treat venous conditions. The present invention is addressed to these needs.

**SUMMARY OF THE INVENTION**

Accordingly, in one aspect, the present invention provides a method for treating venous reflux in a leg of a human. The method includes percutaneously accessing a saphenous vein of the leg, and inserting a percutaneous delivery device in the saphenous vein. An occlusion device is delivered into the saphenous vein from the delivery device, so as to occlude the saphenous vein and prevent reflux therethrough.

In another aspect, the invention provides a method for occluding a vascular vessel. The method includes providing a percutaneous delivery device extending between an entry opening and an exit opening in the vessel. An occluder is delivered into the vessel from the delivery device, wherein the occluder extends between the entry opening and the exit opening.

The invention also concerns a method for occluding a vascular vessel that includes providing first and second openings in the vessel. An occluder is positioned in the vessel and extends between the first and second openings.

In another aspect, the invention provides a method for treating a refluxing greater saphenous vein in a human. The method includes delivering into the greater saphenous vein a resorbable occlusion device so as to occlude and prevent reflux through the vein.

In another embodiment, the invention provides an occlusion device useful for occluding a greater saphenous vein of a human. The occluder device has an elongated occluder body having a length of at least  
5 about 10 centimeters. The occluder body is configured for passage through a percutaneous delivery device and into the greater saphenous vein so as to cause occlusion of the vein.

10 The invention also provides a medical system for vascular occlusion that includes an elongate occluder body having a length of at least about 10 centimeters, and a cannulated device configured for delivery of the elongate occluder body into a vascular vessel.

15 In another aspect, the invention provides a system for delivery of an elongate vascular occluder. The system includes an elongate puncture device for puncturing a vascular vessel, and a guiding catheter  
20 having a lumen for receiving the elongate puncture device. This system further includes a sheath for passage over the guiding catheter, and an elongate guide wire passable through the sheath and configured for attachment to an elongate vascular occluder to pull  
25 the occluder into the sheath.

The invention also provides a medical assembly useful for the delivery of an elongate vascular occluder. The assembly includes an elongate puncture  
30 device for puncturing a vascular vessel, and a guiding catheter having a lumen for receiving the elongate puncture device. A first sheath is provided for



passage over the guiding catheter, and a second sheath is provided for passage through the first sheath and configured to contain the elongate vascular occluder.

5           Further provided by the invention, is a vascular occluder device that includes an elongate occluder body, wherein the body also has an adaptation for attachment to a pulling device.

10           In another embodiment, the invention provides a method for occluding a saphenous vein of a human. The method includes accessing the saphenous vein with an introducer needle. A puncture wire is passed into the saphenous and used to exit the saphenous vein at a  
15           location spaced from the access opening. A sheath is passed from the access opening to the exit opening, and an elongate occluder device is delivered into the saphenous vein from the sheath.

20           The present invention provides improved methods, systems and devices for occluding venous and other vascular vessels. Additional embodiments as well as features and advantages of the invention will be apparent from the further descriptions herein.

**BRIEF DESCRIPTION OF THE DRAWINGS**

FIG. 1 depicts a human leg showing certain venous structures therein.

5

FIG. 2 depicts a human leg showing certain venous structures therein.

FIG. 3 depicts an illustrative embodiment of a human leg having an occlusion device of the invention located in the greater saphenous vein.

10

FIG. 4 depicts an illustrative deployment embodiment of the invention in that portion of the human leg occurring generally between points 13 and 14 in FIG. 1.

15

FIG. 5 depicts an illustrative deployment embodiment of the invention in that portion of the human leg occurring generally between points 13 and 14 in FIG. 1.

20

FIG. 6 depicts an illustrative deployment method of the present invention.

25

FIG. 7 depicts an illustrative deployment method of the present invention.

FIG. 8 depicts an illustrative deployment method of the present invention.

30

FIG. 9 depicts an illustrative deployment method of the present invention.

FIG. 10 depicts an illustrative deployment method  
5 of the present invention.

FIG. 11 depicts an illustrative deployment method of the present invention.

10 FIG. 12 depicts an illustrative deployment method of the present invention.

FIG. 13 depicts an illustrative deployment embodiment of the invention in that portion of the  
15 human leg occurring generally between points 13 and 14 in FIG. 1.

FIG. 14 depicts an illustrative deployment embodiment of the invention in that portion of the  
20 human leg occurring generally between points 13 and 14 in FIG. 1.

FIG. 15 depicts an illustrative deployment embodiment of the invention in that portion of the  
25 human leg occurring generally between points 13 and 14 in FIG. 1.

FIG. 16 depicts an inventive vascular occlusion device in an illustrative deployment embodiment of the  
30 invention.

FIG. 17 depicts an illustrative deployment embodiment of the invention in that portion of the human leg occurring generally between points 13 and 14 in FIG. 1.

5

FIG. 18 depicts an illustrative deployment embodiment of the invention in that portion of the human leg occurring generally between points 13 and 14 in FIG. 1.

10

FIGS. 19A-19H depict an illustrative deployment embodiment of the invention.

FIGS. 20A-20E depict an illustrative deployment embodiment of the invention.

15

FIGS. 20F-20I depict an illustrative deployment embodiment of the invention.

FIGS. 20J-20M depict an illustrative deployment embodiment of the invention.

20

FIGS. 20N-20P depict an illustrative occlusion device and an illustrative deployment embodiment of the invention.

25

FIG. 21 depicts an illustrative occlusion device of the invention.

FIG. 22 depicts an illustrative occlusion device of the invention.

30

FIG. 23 depicts an illustrative occlusion device  
of the invention.

FIG. 24 depicts an illustrative occlusion device  
5 of the invention.

FIG. 25 depicts an illustrative occlusion device  
of the invention.

10 FIG. 26 depicts an illustrative occlusion device  
of the invention.

FIG. 27 depicts an illustrative occlusion device  
of the invention.

15 FIG. 28 depicts an illustrative occlusion device  
of the invention.

FIG. 29A depicts an illustrative occlusion device  
20 of the invention.

FIG. 29B depicts an illustrative occlusion device  
of the invention.

25 FIG. 30A depicts an illustrative occlusion device  
of the invention.

FIG. 30B depicts an illustrative occlusion device  
of the invention.

30 FIG. 31 depicts an illustrative occlusion device  
of the invention.

FIG. 32 depicts an illustrative occlusion device of the invention.

5        FIG. 33 depicts an illustrative occlusion device of the invention.

FIG. 34 depicts an illustrative occlusion device of the invention.

10

FIG. 35A depicts an illustrative occlusion device of the invention.

FIG. 35B depicts an illustrative occlusion device of the invention.

15

FIG. 36 depicts an illustrative occlusion device of the invention.

20        FIG. 37 depicts an illustrative occlusion device of the invention.

FIG. 38 depicts an illustrative occlusion device of the invention.

25

FIG. 39 depicts an illustrative occlusion device of the invention.

FIG. 40 depicts an illustrative deployment embodiment of the invention.

30

DETAILED DESCRIPTION

For the purposes of promoting an understanding of the principles of the invention, reference will now be made to the embodiments illustrated in the drawings and specific language will be used to describe the same. It will nevertheless be understood that no limitation of the scope of the invention is thereby intended, and alterations and modifications in the illustrated devices, and further applications of the principles of the invention as illustrated therein are herein contemplated as would normally occur to one skilled in the art to which the invention relates.

As disclosed above, certain embodiments of the present invention provide methods, devices and systems for achieving occlusion of a vascular vessel such as a saphenous vein. Methods of the invention can be performed, for instance, in order to treat venous reflux through the greater saphenous vein such as that involved in the varicose vein condition.

With reference now more particularly to the figures, shown in Figure 1 is a diagram of a human leg showing certain venous structures therein. In particular, shown is human leg 200 having greater saphenous vein 10 and the femoral vein 11 which adjoin at the sapheno-femoral junction 12. In accordance with certain aspects of the present invention, greater saphenous vein 10 is occluded in a region constituting substantially all of the passage between a point 13 occurring near the medial side of the knee to a point 14

occurring prior to the sapheno-femoral junction 12, as illustrated by the shaded area in Figure 2. Desirably, such occlusion is effective to prevent reflux of venous blood from the sapheno-femoral junction 12 in a direction down toward the medial side of the knee (e.g. at point 13). Such occlusion is effective to treat varicosities that commonly occur in lower portions of the leg, e.g. portions occurring below the knee.

With reference now to Figure 3, in certain forms of the invention, occlusion of the passage of the greater saphenous vein occurring between points 13 and 14 is achieved by an elongate occlusion device 15 that extends from point 13 to point 14, and that may include end portions 16 and 17 that traverse the wall of the greater saphenous vein 10. This may be achieved by deploying occlusion device 15 during a through-and-through percutaneous procedure, e.g. as described hereinbelow. It will be understood, however, that other occlusion devices may be used in aspects of the present invention, including those others disclosed herein as well as conventional devices such as coils.

With reference now to Figure 4, shown is an enlarged view of that portion of the human leg occurring generally between points 13 and 14 of Figure 1. In an illustrative deployment procedure, percutaneous access to the greater saphenous vein 10 is achieved at point 13 using the Seldinger or any other suitable technique. For instance, an access needle can be passed through the skin to access greater saphenous vein 10, and a wire guide 20 can be passed through the



access needle and into the vein 10. Prior to deployment of an occlusion device, wire guide 20 can be used for any number of conventional procedures including catheterization and imaging procedures in order to locate the sapheno-femoral junction 12 and discern a desired exit point 14 for a through-and-through percutaneous procedure. After any such preliminary procedures that are performed, wire guide 20 can be used in a deployment procedure for an occlusion device.

Specifically, referring still to Figure 4, a deployment assembly 21 includes a flexible catheter 22, such as a 5 French radiopaque Teflon catheter, a guide sheath 23, such as a 7 French radiopaque guide sheath, a stiffening cannula received within guide sheath 23 (not shown in Fig. 4), and a delivery sheath 24 received over guide sheath 23. Guide sheath 23 includes a tapered distal end 25 and a bend 26 adjacent the distal end 25, generally corresponding to a bend in the stiffening cannula. Deployment assembly 21 is pre-assembled and threaded along guide wire 20 for the deployment procedure.

With reference now to Figure 5, shown is deployment assembly 21 now received within greater saphenous vein 10 from point 13 to point 14, with the tapered distal end 25 of the guide sheath 23 positioned against the wall of greater saphenous vein 10 using the bend 26 to achieve rotation and placement of the end 25 of the guide sheath 23.

Reference will now be made to Figure 6-12, which provide enlarged cross-sectional views in and around exit point 14 of greater saphenous vein 10 and illustrate various stages of a percutaneous exit procedure. Particularly, shown in Figure 6 is a cross-sectional view of the stage of the procedure illustrated in Figure 5. Tapered end 25 of guide sheath 23 is shown positioned against the wall of greater saphenous vein 10 at point 14. Received immediately within guide sheath 23 is stiffening cannula 28, which for example may be made from 14 gauge stainless steel. Received immediately within stiffening cannula 28 is guide catheter 22; and, received within guide catheter 22 is guide wire 20. In a next stage of the procedure, guide wire 20 and guide catheter 22 are withdrawn from the deployment assembly leaving a condition as illustrated in Figure 7 with guide sheath 23 and stiffening cannula 28 remaining in place.

20

With reference now to Figure 8, a guide catheter 30 and long needle 31 are threaded through the interior of stiffening cannula 28, and needle 31 is used to penetrate the wall of greater saphenous vein 10 as illustrated. Needle 31 is advanced through the adjacent tissue toward the surface of the skin. In certain embodiments of the invention, needle 31 has a needle point of such a sharpness that the needle does not exit the skin, but rather creates a visible bump 32 in the skin from which the location of the needle 31 can be visibly discerned. The skin can be nicked at or near the apex of the bump 32 with a scalpel or other

30

suitable instrument, to allow exit of the needle 31, as illustrated in Figure 9. Subsequently, needle 31 is grasped with forceps or any other suitable means and used to pull deployment assembly 21 through the skin with guide sheath 23 and elements internal thereof exiting first, during which tapered end 25 serves as a dilator to ease exit (see Fig. 10), and eventually exposing end 34 of delivery sheath 24 externally of the skin (see Fig. 11). Subsequently, all components except for delivery sheath 24 are withdrawn, leaving in place delivery sheath 24 with its internal cannula open 35 (see Fig. 12) for use in delivering an occlusion device, for example as described below.

With reference now to Figure 13 shown is a diagram including greater saphenous vein 10 from points 13-14, at the same stage of the procedure as that shown in Figure 12. Delivery sheath 24 is in place in a through-and-through fashion, having a first end 34 exposed through the skin at point 14 occurring near the groin of the patient adjacent the sapheno-femoral junction, and a second end 36 exposed through the skin adjacent the medial portion of the knee of the patient. In this fashion, internal cannula 35 of delivery sheath 24 is open and available for use in delivering a vascular occlusion device.

Referring now to Figure 14, in one embodiment, a relatively stiff guide wire 37 can be threaded through delivery sheath 24. Guide wire 37 has an engaging end 38 including a hooked portion 39 or other suitable adaptation for connection to occlusion device 40.

Occlusion device 40 includes a looped structure 41 or any other suitable connection structure at an end thereof. Hooked portion 39 can be connected to looped structure 41, and guide wire 37 can thereafter be used to draw occlusion device 40 through delivery sheath 24, as generally shown in Figure 15. In particular, Figure 15 illustrates occlusion device 40 having been drawn through delivery sheath 24 to expose an end 27 adjacent looped structure 41 from the skin near the groin of the patient, leaving an end 42 exposed through the skin near the knee of the patient. After this, delivery sheath 24 can be withdrawn, leaving in place only occlusion device 40 in a through-and-through condition with the first end 27 and the second end 42 remaining external of the skin of the patient (see Figure 16). Subsequently, the ends of the occlusion device 40 can be trimmed, and any excess length of device 40 remaining external of the patient can be tucked underneath the skin. The percutaneous access and exit sites can be closed by suturing or any other suitable technique, if necessary.

In some cases, it may be desirable to place more than one occlusion device 40 within the greater saphenous vein 10 of the patient. With reference again to Figures 14-15, if such is desired, more than one guide wire 37 may be passed through delivery sheath 24 to pull through a corresponding number of devices 40, or alternatively, sequential passes can be made of one or more guide wires 37 in order to pull additional devices 40 through the sheath. On the other hand, if sheath 24 has insufficient internal diameter to

accommodate more than one device 40 at a time, again referring to Figure 15, at this stage, a second guide wire 37 can be threaded through sheath such that guide wire 37 and device 40 are both received through sheath

5 24. Sheath 24 can then be withdrawn, leaving in place device 40 and guide wire 37 each in a through-and-through condition. The remaining guide wire 37 can then be used to guide a subsequent deployment assembly 21, and the overall procedure repeated one or more

10 times as described above to place a second device 40, a third device 40, etc.

Upon being positioned within greater saphenous vein 10, occlusion device 40 or devices 40 restrict

15 blood flow in the greater saphenous vein 10 so as to occlude or exclude the same. It is desired that occlusion device 40 be of such a dimension that the material comprising device 40 substantially blocks the internal lumen of greater saphenous vein 10. To this

20 end, the device 40 can have a compressed condition and be adapted to convert to an altered physical configuration after deployment. For example, all or a portion of device 40 may be adapted to expand, unfold, unroll, untwist, harden, or otherwise progress to a

25 condition other than that which it had during deployment and which aids in occluding the vessel. Alternatively or in addition, occlusion device 40 can cause localized thrombus to cause or assist in occluding the lumen of greater saphenous vein 10.

30 Illustrative such expandable occlusion devices can comprise a porous sponge extracellular matrix (ECM) structure and/or a collagenous foam. For additional

information concerning suitable sponge matrix materials and their preparation, reference can be made, for example, to U.S. Pat. No. 6,666,892 and International Publication No. WO03/002168, each of which is hereby  
5 incorporated herein by reference in its entirety.

With reference now to Figure 17, shown is another view similar to that depicted in Figure 14, except illustrating an alternative technique for delivering an  
10 occlusion device. Occlusion assembly 43 includes occlusion device 44 received within an external cannula such as a sheath 45, for coaxial style delivery through delivery sheath 24. For these purposes, illustratively, sheath 24 can be a 12 French sheath and  
15 sheath 45 can be a 10 French sheath. Sheath 45 or other external cannula desirably has an elongate slit 46 therein or another opening or openings along its length. Such opening or openings are beneficial, for example, in that the device 44 can be sterilized after  
20 loading within the sheath 45 using gaseous agents such as ethylene oxide (EO) which penetrate through the opening or openings to contact and sterilize device 44. Procedurally, occlusion assembly 43 is threaded into and through delivery sheath 24 to achieve a through-  
25 and-through condition, whereafter sheaths 24 and 45 are withdrawn leaving occlusion device 44 in place in a through-and-through condition as generally described above. Device 44 can then be trimmed and tucked, and the procedure completed as generally described above.

30

With reference now to Figure 18, shown is a view similar to that depicted in Figure 14, except showing

an alternative occlusion device and delivery system. Particularly, delivery sheath 24 is in place in a through-and-through condition. An occlusion assembly 47 includes an elongate occlusion device 48 received concentrically around an internal guide member 49, such as a guide wire, and if desired is provided with an end piece 50 with a tapered end to assist in traversal of the occlusion device 48 through the delivery sheath 24. The assembly 47 including occlusion device 48, guide member 49, and end piece 50 has sufficient column strength and integrity to be pushed through delivery sheath 24 from end 36 to end 34, leaving occlusion device 48 in a through-and-through condition. Internal guide member 49 with end piece 50 and sheath 24 can then be withdrawn, and the occlusion device 48 trimmed and tucked prior to completing the procedure as described above.

With reference to Figures 19 and 20, illustrated are alternative methods for delivering occlusion devices by through-and-through percutaneous procedures. Taking first Figure 19, Figure 19A illustrates initial access to a vascular vessel 60 through the skin 61 via introducer needle 62, which is used to deliver guide wire 63 to the vessel 60. Guide wire 63 is used to guide an assembly including a dilator 64 and an outer sheath 65 into the vessel 60, as shown in Figure 19B. The guide wire 63 and dilator 64 are withdrawn, leaving in place sheath 65 as shown in Fig. 19C. Fig. 19D shows a stage of the procedure in which a second percutaneous access is provided via introducer needle 66, with the needle 66 penetrating

sheath 65. A guide wire 68 is introduced through needle 66 and traverses sheath 65 thus exiting the initial percutaneous access site. As shown in Fig. 19E, sheath 65 is withdrawn over guide wire 68 leaving  
5 in place guide wire 68 in a through-and-through condition as shown in Fig. 19F. An assembly including dilator 69 and sheath 70 is then introduced over guide wire 68 as shown in Fig. 19G, and the dilator 69 and guide wire 68 are withdrawn thereby leaving in place  
10 sheath 70 in a through-and-through condition as shown in Fig. 19H. Sheath 70 can then be used for the introduction of an occlusion device in a suitable manner including those described hereinabove.

15 With reference now to Figs. 20A-20E, shown is an alternative procedure for establishing a through-and-through sheath for delivery of an occlusion device. Fig. 20A illustrates an early stage in the procedure wherein access to vascular vessel 70 is provided  
20 through skin 71 at two locations. At a first location, introducer needle 72 accesses vessel 70 and is used to deliver a "J" guide wire 73 into vessel 70. At another location, introducer needle 74 is used to access vessel 70 and deliver guide wire 75 to vessel 70. As  
25 illustrated in Fig. 20B, a catheter 76 is advanced over the "J" guide wire 73, and an assembly including catheter 77 and overlying sheath 78 is advanced over guide wire 75. After introduction of the sheath 78 into vessel 70, guide wire 75 and catheter 77 are  
30 withdrawn from sheath 78. At this stage, as illustrated in Fig. 20C, "J" guide wire 73 and its accompanying catheter 76 are advanced into the cannula



of sheath 78. Advancement is continued until catheter 76 and "J" guide wire 73 exit the opposite end of sheath 78 as shown in Fig. 20D. Catheter 76 can optionally have a segment (e.g. about 3 to 10 cm in length) proximal to the distal tip that tapers to a slightly enlarged external diameter. This segment would fit snugly into the sheath 78, and would create a transitioning external diameter that would ease exit of the sheath 78 from the second puncture site. Fig. 20E shows the sheath 78 thereafter established in a through-and-through condition after withdrawal of the catheter 76 and "J" guide wire 73 from the sheath 78. Sheath 78 can then be used for the deployment of an occlusion device in any suitable manner including those described above.

Although certain procedures have been described above for the delivery of occlusion devices, it will be understood that other modes of delivery of occlusion devices are also suitable in the present invention. For example, procedures involving only a single point of percutaneous access can be conducted, for instance wherein a delivery sheath is established through a percutaneous access site and into the vascular vessel to be occluded, and an occlusion device is delivered from the sheath using any suitable technique including pushing the occlusion device from the end of the sheath, e.g. as the sheath is withdrawn. In situations where needed, techniques and/or device adaptations can be employed to help to prevent withdrawal of the occlusion device as the sheath is being withdrawn from the patient over the occlusion device. These include

for example the use of anchoring portions connected to the occlusion device that forcibly contact vessel walls and resist migration and/or local external compression (e.g. particularly in the case of shallow vessels) to collapse the vessel walls against a leading portion of the occlusion device exposed from the end of the sheath and/or fixing an end, or a portion of the body, of the occlusion device to the vasculature using a suitable securing means, such as one or more sutures or staples, to facilitate maintaining the position of the occluder device as the sheath is withdrawn.

As well, as a modification of a through-and-through percutaneous procedure, a single percutaneous access to a vein or other vessel through the skin can be provided, wherein at a spaced location of the accessed vessel, the vessel is again penetrated, but not the skin. One end of an elongate occlusion device can then be passed through the second penetration of the vessel and anchored in the surrounding tissue, and the percutaneous access site finished off as described above in connection with the through-and-through procedures. In the context of occluding the greater saphenous vein, such adaptations and/or techniques can be used with the percutaneous access site provided either at the knee level or near the groin in the area of the sapheno-femoral junction, or any appropriate location in between. As well, upon establishing a sheath containing a vascular occlusion device within a vessel to be occluded, a second vascular access sight can be provided near the end of the sheath, and a snare basket, or other suitable device for maintaining hold

on the end of the vascular occlusion device, can be used to maintain the position of the occlusion device as its overlying sheath is withdrawn from the first percutaneous access site. Further, it is contemplated  
5 within certain embodiments of the invention that cut-down or other surgical procedures could be used in providing access to vascular vessels for delivery of vascular occlusion devices.

10 To illustrate further percutaneous delivery methods, shown in Figures 20F-20I is one descending delivery method involving only a single point of access. As shown in Figure 20F, a guide wire 51 such as a J-wire is established in the greater saphenous  
15 vein via a percutaneous entry 52 near the groin. Subsequently, using the wire 51, a cannulated device 53 such as a catheter or sheath is established in the vein (Figure 20G), and an occluder device 54 is delivered to the vein through the cannulated device 53 (Figure 20H),  
20 e.g. by pushing or otherwise delivering the occluder device 54 out of the cannulated device 53 and withdrawing the cannulated device 53, potentially in a simultaneous operation. In one mode of practice, the occluder device 54 can have a length sufficient to  
25 extend from the vein and out of the percutaneous exit 52, as shown in Figure 20H. The occluder device can then be trimmed and if desired secured at the site of percutaneous entry 52 (Figure 20I). Figures 20J-20M illustrate a similar one-site percutaneous delivery,  
30 except using an ascending approach with entry just above the knee.

To illustrate yet further percutaneous delivery methods and occlusion devices, shown in Figures 20N-20P is an alternative occlusion device and delivery system utilizing a single point of access. In this

5   embodiment, turning to Figure 20N, the occlusion device 186 comprises a ribbon or band 172 attached to a fixation device 174, such as a flexible tube or rod, using one or more sutures 180, or other suitable securing means. Optionally, each end of the fixation

10   device 176, 178 can terminate with one or more barbs, or other suitable anchoring means. The occlusion device 186 can be deployed by first locating a deployment sheath 182 in a vascular vessel 170. Next, the ribbon 172 portion of the occlusion device 186 can

15   be loaded into a delivery sheath 184 while leaving the fixation device 174 external to the distal end 185 of the delivery sheath 184. Next, the delivery sheath 184, containing the occlusion device 186, can be placed inside the deployment sheath 182 in a manner that

20   compresses or flexes the fixation device 174 and the delivery sheath 184 can be pushed through the deployment sheath 182. As the fixation device 174 breaches the distal end of the deployment sheath 183, it will expand, thereby anchoring itself into the wall

25   of the vessel 170 (see Fig. 200). After the fixation device 174 anchors, the deployment sheath 182 and delivery sheath 184 can be retracted to deploy the ribbon 172 into the vessel (see Fig. 20P).

30   Alternatively, a plurality of occlusion devices 186 can be deployed in the same vascular vessel 170 according to the above method to achieve suitable occlusion and/or thrombosis of the vascular vessel 170. Still

alternatively, the ribbon 172 can be folded over and secured to the fixation device 174, thereby forming two legs or bands for achieving occlusion.

5           Figures 21 to 35B illustrate various embodiments of vascular occlusion devices of and for use in the invention. Fig. 21 shows vascular occlusion device 80 having an occlusion body 81, and first end 82, and a second end 83. Device 80 has a length "L" sufficient  
10 to occlude the length of the passage for which occlusion or ablation is desired. In accordance with certain embodiments of the invention, the device 80 will have a length sufficient and will be positioned so as to traverse at least one vessel that branches from  
15 the vessel to be occluded, for instance a perforator or communicator vein branching from a larger vein to be occluded such as a saphenous vein, e.g. the greater saphenous vein. In the context of greater saphenous vein occlusion procedures as described above, length  
20 "L" will be sufficient to traverse the greater saphenous vein from position 13 to position 14, desirably having sufficient excess length to exit percutaneous access sites at those locations for processing as described. These same considerations may  
25 be applied to the other vascular occlusion devices described herein.

Fig. 22 shows occlusion device 84 having an occlusion body 85, with first and second ribbons 86 and  
30 87 of occlusion material. Ribbons 86 and 87 are adjoined to one another integrally by an area 88 of occlusion material.

Fig. 23 shows occlusion device 89 having an occlusion body 90 with first and second legs or ribbons of material 91 and 92. Ribbons 91 and 92 are formed by  
5 creating a fold 93 in an integral longer sheet of material. If desired, a wire loop 94 or any other suitable tethering adaptation can be positioned around fold 93 or otherwise connected to the occlusion body 90.

10

Illustrated in Fig. 24 is an occlusion device 95 having occlusion body 96 with a first end 97 and a second end 98 thereof. Occlusion body 96 includes a plurality of cuts or slits along the length thereof to  
15 form flares or legs 99 which increase the surface area for contact with blood after deployment and enhance the occlusive character of the device 95, e.g. by promoting thrombus.

20

Fig. 25 shows occlusion device 100 having a plurality of ribbons 101, 102, 103, and 104 connected by an element 105 such as a wire loop threaded through ends of the ribbons.

25

Shown in Fig. 26 is occlusion device 106 formed as a roll of occlusion material to provide a generally cylindrical occlusion body 107. Additionally, occlusion body 107 could be partially or completely  
30 slit along plane 108 and potentially additional planes, to provide modified configurations having increased surface area for blood contact.

Referring now to Fig. 27, shown is occlusion device 109 having an occlusion body 110, formed by creating multiple folds 111 in a sheet of occlusion material. In this regard, it will be understood that  
5 this folded adaptation and other adaptations described herein can be designed to render the occlusion devices more compact and less voluminous for delivery, but which devices expand, unfold, or otherwise take on an increased dimension after delivery to facilitate the  
10 occlusion function.

Fig. 28 shows an occlusion device 112 having an occlusion body 113 formed as a roll 114 of occlusion material. The external surface of occlusion body 113  
15 has been contoured to create a plurality of bumps, flares or other protuberances 115 along the length thereof.

Fig. 29A and 29B illustrate additional occlusion  
20 devices of the invention. Fig. 29A shows occlusion device 116 having an occlusion body 117 formed of an occlusion material. Body 117 includes a plurality of cuts or slits 118, for example to provide a mesh configuration, to increase surface area for blood  
25 contact. Additionally, occlusion body 117 can be rolled (see arrows) in order to form an alternate occlusion device 119 shown in Figure 29B. Device 119 includes a generally cylindrical occlusion body 120 having irregular, raised loops or others portions of  
30 material 121 flaring from its surface.

Additional embodiments of occlusion devices of the invention are shown in Figs. 30A and 30B. Fig. 30A shows an occlusion device 122 including an occlusion body 123 having a plurality of legs or ribbons of material 124 established along an edge thereof by cutting or slitting material. If desired, occlusion body 123 can be rolled diagonally from a corner thereof (see arrows) in order to provide occlusion device 125 illustrated in Fig. 30B. Device 125 includes a generally cylindrical body 126 and in its rolled configuration ribbons 124 extend or flare from the surface thereof for increased blood contact.

In other occlusion devices of the invention, it is contemplated that occlusion material in any suitable form, such as a ribbon, band, foam, cylinder, or the like, can be combined with elements for anchoring one or both ends of the occlusion device within a vascular vessel. Illustratively, shown in Fig. 31 is an occlusion device 127 having an occlusion body 128 made out of an occlusion material, and an elongate wire or other element 129 received within occlusion body 128. Wire or other element 129 exits the ends of the occlusion body 128, and provides coils 130 and 131 which can be configured to expand and provide points of securement of device 127 within a vascular vessel. As well, if desired, coils 130 and 131 may have synthetic fibers attached thereto to facilitate thrombus formation, for example as conventionally incorporated on commercial platinum or stainless steel embolization and occlusion coils. Further, while the occlusion body 128 is shown in tubular form, it can occupy any



suitable shape or form, such as a ribbon, band, foam, or the like.

5 Shown in Fig. 32 is occlusion device 132 similar to that depicted in Figure 31, including an occlusion body 133, and an internal wire or other element, and securement adaptations 134 and 135 provided by a plurality of diverging filaments or wire elements such as those found in vascular filters.

10

With reference to Fig. 33-35B, shown are various occlusion devices of the invention including occlusion bodies and self-expanding or forcibly (e.g. balloon) expandable stents secured to the ends of the occlusion  
15 bodies for providing points of securement within a vascular vessel. Fig. 33 shows device 136 having occlusion body 137, such as a strip or tube of occlusion material, having first and second square stents 138 and 139 attached to the ends thereof.  
20 Square-shaped stents 138 and 139 can, for example, be constructed as described in U.S. Patent Nos. 6,200,336 and 6,508,833. Fig. 34 discloses a vascular occlusion device 140 having an occlusion body 141 such as a strip or tube of occlusion material having secured at the  
25 ends thereof stents such as those ZILVER® stents sold by Cook, Inc., Bloomington, Indiana (elements 142 and 143). Fig. 35A shows an occlusion device 144A having an occlusion body 145A such as a strip or tube of occlusion material having attached to ends thereof Z-  
30 stents 146A and 147A such as those sold by Cook, Inc. Fig. 35B discloses an occlusion device 144B similar to that depicted in Fig. 35A but further comprising barbs

148 attached to the struts of the stents 146B, 147B located at each device end. For more information on suitable barb configurations and methods of placing or mounting barbs on stents, reference can be made to U.S. Pat./App. Nos. 5,720,776 and 2001/0039450.

In the above-described embodiments incorporating stents, coils, filter-like elements or other anchor devices, attachment of the occluder material to the anchor device may be achieved by suturing, bonding, 10 heat-induced welding (including laser welding), or any other suitable technique. As well, where stents are utilized, any lumen of the stent(s) may be spanned and closed by a biomaterial, including a remodelable 15 biomaterial as described herein, to facilitate the occlusion procedure.

The material used in the formation of vascular occlusion devices of the invention can be any material 20 suitable for occluding a vascular vessel of interest. In this regard, the occlusion material may be a synthetic material such as a polymeric material, a naturally-derived material, or a metallic material such as stainless steel. Illustrative synthetic materials 25 may include biodegradable or non-biodegradable materials. These include, for example, synthetic biocompatible polymers such as cellulose acetate, cellulose nitrate, silicone, polyethylene teraphthalate, polyurethane, polyamide, polyester, 30 polyorthoester, polyanhydride, polyether sulfone, polycarbonate, polypropylene, high molecular weight polyethylene, polytetrafluoroethylene, woven DACRON®,

polyvinyl alcohol foam, a hydrogel, or mixtures or copolymers thereof; polylactic acid, polyglycolic acid or copolymers thereof, a polyanhydride, polycaprolactone, polyhydroxy-butyrates, valerate, 5 polyhydroxyalkanoate, or another biodegradable polymer.

Reconstituted or naturally-derived collagenous materials and/or another source of tissue, such as vascular vessels, can also be used as occlusion 10 materials in the present invention. Such materials that are at least bioresorbable will provide advantage in the present invention, with materials that are bioremodelable and promote cellular invasion and ingrowth providing particular advantage.

15 Bioremodelable materials may be used in this context to promote cellular growth within the lumen of the occluded vessel. This helps to guard against re-establishment of patency of the vessel through biologic processes after the occlusion procedure is completed.

20 Suitable bioremodelable materials can be provided by collagenous extracellular matrix materials (ECMs) possessing biotrophic properties. These can be delivered to the vessel in a lyophilized or otherwise dried, or hydrated state, or additionally or 25 alternatively in a gel or otherwise flowable (and optionally hardenable) state. For example, suitable collagenous materials include ECMs such as submucosa, renal capsule membrane, dermal collagen, dura mater, pericardium, serosa, peritoneum or basement membrane 30 layers, including liver basement membrane. Suitable submucosa materials for these purposes include, for

instance, intestinal submucosa including small intestinal submucosa, stomach submucosa, urinary bladder submucosa, and uterine submucosa.

5           As prepared and used, the submucosa material and any other ECM used, may optionally retain growth factors or other bioactive components native to the source tissue. For example, the submucosa or other ECM may include one or more growth factors such as basic  
10   fibroblast growth factor (FGF-2), transforming growth factor beta (TGF-beta), epidermal growth factor (EGF), and/or platelet derived growth factor (PDGF). As well, submucosa or other ECM used in the invention may include other biological materials such as heparin,  
15   heparin sulfate, hyaluronic acid, fibronectin and the like. Thus, generally speaking, the submucosa or other ECM material may include a bioactive component that induces, directly or indirectly, a cellular response such as a change in cell morphology, proliferation,  
20   growth, protein or gene expression.

          Further, in addition or as an alternative to the inclusion of such native bioactive components, non-native bioactive components such as those synthetically  
25   produced by recombinant technology or other methods, may be incorporated into the submucosa tissue. These non-native bioactive components may be naturally-derived or recombinantly produced proteins that correspond to those natively occurring in the ECM  
30   tissue, but perhaps of a different species (e.g. human proteins applied to collagenous ECMs from other animals, such as pigs). The non-native bioactive

components may also be drug substances. Illustrative drug substances that may be incorporated into and/or onto the occlusion devices include, for example, antibiotics, thrombus-promoting substances such as blood clotting factors, e.g. thrombin, fibrinogen, and the like. These substances may be applied to the occlusion device as a premanufactured step, immediately prior to the procedure (e.g. by soaking the material in a solution containing a suitable antibiotic such as cefazolin), or during or after deployment of the occlusion device in the patient.

Submucosa or other ECM tissue used in the invention is preferably highly purified, for example, as described in U.S. Patent No. 6,206,931 to Cook et al. Thus, preferred ECM material will exhibit an endotoxin level of less than about 12 endotoxin units (EU) per gram, more preferably less than about 5 EU per gram, and most preferably less than about 1 EU per gram. As additional preferences, the submucosa or other ECM material may have a bioburden of less than about 1 colony forming units (CFU) per gram, more preferably less than about 0.5 CFU per gram. Fungus levels are desirably similarly low, for example less than about 1 CFU per gram, more preferably less than about 0.5 CFU per gram. Nucleic acid levels are preferably less than about 5  $\mu\text{g}/\text{mg}$ , more preferably less than about 2  $\mu\text{g}/\text{mg}$ , and virus levels are preferably less than about 50 plaque forming units (PFU) per gram, more preferably less than about 5 PFU per gram. The ECM material used in the invention is preferably disinfected with an oxidizing agent,

particularly a peracid, such as peracetic acid. These and additional properties of submucosa or other ECM tissue taught in U.S. Patent No. 6,206,931 may be characteristic of the submucosa tissue used in the present invention.

When used in the invention, collagenous materials such as ECMs can be in a hydrated or dried state in the product as packaged and/or when delivered. Suitable drying techniques include, for example, air drying, lyophilization techniques including freeze-drying and evaporative cooling, and vacuum-drying e.g. as occurs in vacuum pressing processes. In addition, occluder devices of the invention can include collagenous materials such as ECM materials, a portion of which have been dried by one technique and another portion of which have been dried by another, differing technique. Illustratively, an occluder device may be provided with a more pliant portion that has been dried under lyophilization conditions, and a less pliant portion that has been dried by air-drying or under vacuum pressing conditions. For instance, shown in Figure 36 is an occluder device 150 that includes a relatively pliant, lyophilized, fan-folded portion 151 attached at one end to a more rigid vacuum-pressed portion 152 which may be formed as a cord or rope. In this manner, the device 150 can be advanced into a vein or other vessel (e.g. from a sheath or other cannulated device) with the fan-folded portion 151 as the leading end, while using the more rigid vacuum-pressed portion 152 to push the fan-folded portion 151. The vacuum-pressed portion 152 can optionally be sufficiently long to

extend out of the percutaneous entry site and effectively serve as a pusher rod. After withdrawal of the sheath, the vacuum-pressed portion can be trimmed at the skin and tucked into the percutaneous access site.

Figure 37 shows another occluder device embodiment including a collagenous material such as an ECM, and a more rigid component. Occluder device 153 includes an elongate body 154 of ECM or other collagenous material, and a more rigid elongate element 155 connected to the body 154. For example, element 155 can be connected to the body 154 at least at or near the distal end 156 of the body 154, which will serve as the leading end of the device 153 during delivery, e.g. from a sheath or other cannulated device. In some embodiments, element 155 will be connected to body 154 at multiple points or continuously along the length of body 154. Element 155 can have a length sufficient to extend from the cannulated device. Thereby, element 155 can be held in place during withdrawal of the cannulated device, to facilitate maintaining the position of the distal end 156 of body 154 in the vein or other vessel during such withdrawal. In this regard, in one convenient embodiment, a splitable sheath or other cannulated device can be employed during delivery, and split around rigid element 155 as the sheath is withdrawn from the patient.

If element 155 is made from a permanently implantable material, element 155 can be trimmed and left implanted in the patient along with body 154. For

example, element 155 may be comprised of a bioresorbable and/or bioremodelable material such as a synthetic polymer or collagen, including an ECM material. When element 155 and body 154 each comprise an ECM such as submucosa or another collagenous material, element 155 may for example be air-dried or vacuum pressed to be more rigid than body 154, which may be lyophilized. In these embodiments, element 155 and body 154 may be formed of a single piece of material, or multiple pieces of material attached together, e.g. by bonding or suturing with a bioresorbable or other material.

Shown in Figure 38 is another occluder device embodiment 157 having an elongate body 158 and a distal anchoring end 159. Distal anchoring end 159 is configured to expand and contact the walls of the vein or other vessel after delivery from the end of a cannulated device, sufficiently to facilitate maintaining the end 159 and connected body 158 in place during withdrawal of the cannulated device. Distal anchoring end 159 may be made from the same material or a different material as elongate body 158. For example, body 158 and distal anchoring end 159 may both be made of a resorbable substance such as a collagenous material (e.g. containing an ECM such as submucosa), with anchoring end 159 being comprised of a relatively highly expandable porous material such as sponge or foam, and body 158 being comprised of a less expandable ribbon. The anchoring end 159 and body 158 may for example be integrally formed, or may be separate pieces attached to one another by bonding, sutures or other



means. As in certain other embodiments described herein, the ribbon or other body 158 may be sufficiently long to extend to the percutaneous exit site, where it can be trimmed after delivery.

5

As illustrated in Figure 39, in another embodiment 157A similar to that described in conjunction with Figure 38, an anchoring end 159A is provided by a coiled portion that is collapsed during receipt within the cannulated delivery device, and which radially expands upon exiting the device. When an ECM-  
10 containing or other collagenous material is used for anchoring end 159A, the material can be lyophilized, vacuum-pressed or otherwise dried in the coiled or  
15 other radially-expanding configuration, to set a shape memory to the material.

As shown in Figure 40, devices 157 and 157A may be delivered in a dual-sheath system 160, in which an  
20 inner sheath 161 extends to the trailing edge 162 of the anchoring end 159,159A, and an outer sheath 163 extends over the anchoring end 159,159A. In this manner, after advancement into the vessel to be occluded, outer sheath 163 can be withdrawn to release  
25 anchoring end 159,159A to expand and contact the vessel walls, whereafter inner sheath 161 can be withdrawn while anchoring end 159,159A resists withdrawal of the device 157,157A from the vessel. It will be understood that such a dual-sheath system may be used in  
30 conjunction with any similar occluder device having an expandable anchoring feature and an elongate portion,

including expandable features such as stents, filter-type baskets, coils, and the like.

It will be also understood that devices similar to those shown in Figures 38 and 39, except having more than one anchoring portion, e.g. having anchoring ends at both ends, are also contemplated as being within the invention. Such devices having an anchoring portion at each end may be deployed fully into the lumen of the vein or other vessel to be occluded, with the anchoring ends contacting the vessel walls and stabilizing the position of the devices in the vessel.

Occlusion devices of the invention will generally be of sufficient dimension to achieve occlusion of the desired stretch of vascular vessel, either alone or in combination with other similar or differing devices. In certain embodiments, the occlusion device will have a length of at least about 10 cm, and in many situations at least about 20 cm. Indeed, for preferred occlusion procedures involving a significant stretch of an artery or vein, occlusion devices having lengths greater than 30 cm will be used. Illustratively, in the occlusion of the greater saphenous vein in human adolescents or adults, occlusion devices having lengths of at least about 40 cm or 50 cm can be used.

While discussions above focus upon occluding the greater saphenous vein via access at the knee level, the greater saphenous vein may also be accessed at a lower level, e.g. near the ankle. During such access, any or all of the greater saphenous vein occurring

between the ankle and the sapheno-femoral junction may be subjected to occlusion. Other veins in the leg(s) that may be involved in the varicose vein condition may also be occluded, alternatively or in addition to the greater saphenous vein. For example, the lesser saphenous vein, or varicose veins themselves, may be occluded and obliterated in accordance with the invention. Further, other veins or arteries in the leg(s) or elsewhere in the body may be occluded within the scope of the present invention.

Percutaneously-conducted occlusion procedures of the invention will typically be performed under local anesthesia. In addition, after completion of the procedure, it may be beneficial to use graduated compression stockings in the occluded area, for example for a week or more. Compression of the occluded area may serve to facilitate permanent closure of the occluded vessel, for example when applied during a remodeling period during which tissue ingrowth into the occluded lumen occurs.

Sheaths, dilators, wire guides and needles used in the present invention can all be conventional marketed products or modifications thereof. For example, sheaths can be formed from PTFE (e.g. Teflon) or polyamide (e.g. Nylon) material, or a combination of materials such as an assembly including an inner layer of PTFE, a flat wire coil over the PTFE for kink resistance, and a polyamide (Nylon) outer layer to provide integrity to the overall structure and a smooth surface (e.g. as in the Flexor sheath, Cook, Inc.).

Dilators can be made from conventional dilator/catheter type materials such as polyethylene, polyamide, polyurethane or vinyl, or any combination of these materials. Fittings provided for sheath/dilator assemblies can be conventional elements such as luer locks, and the dilator can have a fitting allowing it to be locked to the sheath during insertion and manipulation. Catheters can be made from conventional materials such as polyethylene, polyamide, PTFE, polyurethane, and other materials.

Delivery sheaths used in the invention will have a lumen diameter sized to allow for the introduction of a sufficient amount of occlusion material to occlude the artery or vein of interest. Illustratively, the inner diameter (I.D.) of the final delivery sheath can range from about 8 French up to about 40 French.

As is conventional, the distal ends of the catheters, sheaths, dilators, wires or other components used in percutaneous procedures can include markers that can be X-ray, sonographically, or otherwise non-invasively visualized to identify their location during the procedure. Metallic bands of stainless steel, tantalum, platinum, gold, or other suitable materials, which include a dimple pattern, can serve the purpose for both ultrasound and X-ray identification. As well, distal and/or proximal ends and/or other locations on occluder devices of the invention may include markers for non-invasive imaging, including imageable materials such as those discussed above as well as substances that can be applied to ECMs or other collagenous

materials, e.g. substances containing tantalum, barium, iodine, or bismuth, e.g. in powder form.

5           The invention also encompasses medical kits, such  
as, for example, an elongate puncture device, a  
cannulated guiding device, a sheath, a guide wire  
configured for engagement of an occlusion device, and  
an inventive occlusion device, sealed within sterile  
medical packaging. The final, packaged products are  
10 provided in a sterile condition. This may be achieved,  
for example, by gamma, e-beam or other irradiation  
techniques, ethylene oxide gas, or any other suitable  
sterilization technique, and the materials and other  
properties of the medical packaging will be selected  
15 accordingly. The occlusion device may be packaged wet  
or after it is dried.

          While the invention has been illustrated and  
described in detail in the foregoing description, the  
20 same is to be considered as illustrative and not  
restrictive in character, it being understood that only  
the preferred embodiment has been described and that  
all changes and modifications that come within the  
spirit of the invention are desired to be protected.  
25 All publications cited herein are hereby incorporated  
by reference in their entirety as if each had been  
individually incorporated by reference and fully set  
forth. In addition, United States Provisional Patent  
Application Serial No. 60/470,611, filed May 14, 2003  
30 and entitled, "Vessel Closure Device, Delivery  
Apparatus and Method of Delivering the Closure Device,"

is hereby incorporated herein by reference in its entirety.

## WHAT IS CLAIMED IS:

- 5           1. A method for treating venous dysfunction  
in a leg of a human, comprising:  
          providing at least one percutaneous access to a  
          saphenous vein of the leg;  
          inserting a delivery device into the saphenous  
10   vein through the percutaneous access; and  
          delivering an occlusion device to the saphenous  
vein with the delivery device.
2. A method according to claim 1, wherein  
15   the saphenous vein is the greater saphenous vein.
3. A method according to claim 1, wherein  
the saphenous vein is the lesser saphenous vein.
- 20           4. A method according to any one of claims  
1-3, wherein the occlusion device is resorbable.
5. A method according to any one of claims  
1-4, wherein the occlusion device is collagenous.
- 25           6. A method according to any one of claims  
1-5, wherein the occlusion device comprises an  
extracellular matrix material.
- 30           7. A method according to claim 6, wherein  
the extracellular matrix material comprises submucosa,  
serosa, pericardium, dura mater, peritoneum, or dermal  
collagen.

8. A method according to claim 5, wherein the occlusion device comprises reconstituted collagen.

9. A method according to any one of claims 1-8, wherein the occlusion device has a length of at least about 10 cm.

10. A method according to any of claims 1-9, wherein the occlusion device is delivered so as to traverse a junction of at least one perforator vein with the saphenous vein.

11. A method according to any of claims 1-10, wherein the occlusion device extends between a first and second surgical opening in the saphenous vein.

12. A method according to any of claims 1-11, wherein the occlusion device has a length of at least about 20 cm.

13. A method according to any of claims 1-12, wherein the occlusion device comprises submucosa.

14. A method according to any of claims 1-13, wherein the occlusion device comprises an elongate body configurable to a first, compressed condition and expandable upon delivery to a second, expanded condition.

15. A method for occluding a vascular vessel, comprising:



providing a first opening and a second opening in the vessel; and

positioning an occlusion device in the vessel extending between the first opening and second opening.

5

16. A method according to claim 15, wherein the vascular vessel is a vein.

17. A method according to claim 16, wherein  
10 the vein is in a human leg.

18. A method according to claim 17, wherein the vein is a saphenous vein.

19. A method according to claim 18, wherein  
15 the saphenous vein is a greater saphenous vein.

20. A method according to claim 18, wherein the saphenous vein is a lesser saphenous vein.

20

21. A method according to claim 18, wherein the saphenous vein includes both the greater and lesser saphenous vein.

22. A method according to any of claims 15-  
25 21, wherein the first and second openings are created percutaneously.

23. A method according to claim 22, wherein  
30 the first opening is created by percutaneous entry, and the second opening is created by an elongate puncture device passed through the vascular vessel from the

first opening to a position spaced from the first opening.

24. A method according to any one of claims  
5 15-23, wherein the occlusion device comprises a resorbable material.

25. A method according to claim 24, wherein  
the occlusion device comprises a collagenous material.  
10

26. A method according to any one of claims  
15-25, wherein the occlusion device comprises an  
extracellular matrix material.

27. A method according to claim 26, wherein  
the extracellular matrix material comprises submucosa,  
serosa, pericardium, dura mater, peritoneum, or dermal  
collagen.  
15

28. A method according to claim 25, wherein  
the occlusion device comprises reconstituted collagen.  
20

29. A method according to any one of claims  
15-28, wherein the occlusion device has a length of at  
least about 10 cm.  
25

30. An occlusion device useful for occluding  
a vascular vessel of a human, comprising an occluder  
body having a length of at least about 10 cm, the  
occluder body configured for percutaneous delivery into  
the vascular vessel so as to cause occlusion of the  
vascular vessel.  
30

31. An occlusion device according to claim 30, wherein the occluder body has a length of at least about 20 cm.
- 5
32. An occlusion device according to claim 30, wherein the occluder body has a length of at least about 30 cm.
- 10
33. An occlusion device according to claim 30, wherein the occluder body has a length of at least about 40 cm.
- 15
34. An occlusion device according to any one of claims 30-33, wherein the occluder body comprises an elongate core body and at least one thrombogenic element extending from the elongate core body.
- 20
35. An occlusion device according to any one of claims 30-34, wherein the occluder body is configured in a first, compressed condition and is expandable upon delivery to a second, expanded condition.
- 25
36. An occlusion device according to claim 35, wherein the occluder body in said first, compressed condition includes at least one rolled or folded portion.
- 30
37. An occlusion device according to claim 36, wherein the occluder body in said first, compressed condition includes a plurality of folds.

38. An occlusion device according to any one of claims 30-37, wherein the occluder body comprises a resorbable material.

5           39. An occlusion device according to any one of claims 30-38, wherein the occluder body comprises a collagenous material.

          40. An occlusion device according to claim  
10 39, wherein the occluder body comprises an extracellular matrix material.

          41. An occlusion device according to claim  
40, wherein the extracellular matrix material comprises  
15 submucosa, serosa, pericardium, dura mater, peritoneum, or dermal collagen.

          42. An occlusion device according to claim  
41, wherein the extracellular matrix material comprises  
20 submucosa.

          43. A medical kit for vascular occlusion,  
comprising:  
          an occlusion device according to any one of  
25 claims 30-42; and  
          at least one additional device for  
percutaneous passage into the vascular vessel.

          44. A medical kit according to claim 43,  
30 wherein the at least one additional device is a  
delivery device for delivering the occlusion device  
into the vascular vessel.

45. A medical kit according to claim 44, wherein the delivery device comprises a lumen, and wherein the occlusion device is receivable in and deliverable from the lumen.

5

46. A medical kit useful for delivery of a vascular occlusion device, the kit comprising:

an elongate puncture device for passage through and providing percutaneous exit from a vascular vessel;

a cannulated guiding device having a lumen for receiving the elongate puncture device;

a sheath passable over the cannulated guiding device; and

an elongate device passable through the sheath and configured for engagement with the elongate vascular occlusion device to force the occlusion device through the sheath.

47. A medical kit useful for delivery of a vascular occlusion device in a vascular vessel, the kit comprising:

an elongate puncture device for passage through and providing percutaneous exit from a vascular vessel;

a cannulated guiding device having a lumen for receiving the elongate puncture device;

a first sheath passable over the cannulated guiding device; and

a second sheath passable through the first sheath and configured to contain the vascular occlusion device.

48. A medical kit according to claim 47,  
wherein the second sheath contains a preloaded vascular  
occlusion device.

5

49. A medical kit according to claim 47 or  
48, wherein the vascular occlusion device is configured  
for occlusion of a human greater saphenous vein.

10

50. A medical kit according to claim 48,  
wherein the preloaded vascular occlusion device is an  
occlusion device according to any one of claims 30-42.

15

51. A medical kit according to claim 47,  
also comprising an occlusion device.

20

52. A medical kit according to claim 51,  
wherein the occlusion device is an occlusion device  
according to any one of claims 30-42.

25

53. A medical assembly for delivery of a  
vascular occlusion device, comprising:  
a vascular occlusion device according to any  
one of claims 30-42;  
a delivery device; and  
wherein said vascular occlusion device is  
engaged with said delivery device.

30

54. A medical assembly according to claim  
53, wherein the delivery device comprises a lumen, and  
wherein the vascular occlusion device is engaged with  
the delivery device by receipt within the lumen.

55. A medical assembly according to claim 53, wherein the vascular occlusion device is engaged with the delivery device by receipt over the delivery device.

5

56. A medical assembly according to claim 53, wherein the vascular occlusion device is engaged with the delivery device by attachment at or adjacent to an end of the delivery device.

10

57. A method for treating a refluxing saphenous vein of a human, comprising:  
percutaneously delivering into the greater saphenous vein an occlusion device so as to occlude and prevent reflux through the vein.

15

58. A method according to claim 57, wherein the occlusion device is an occlusion device according to any of claims 30-42.

20

59. A method according to claim 57 or 58, wherein the occlusion device is delivered so as to traverse at least one junction between a perforator and the saphenous vein.

25

60. A method according to any one of claims 57-59, wherein the saphenous vein is the greater saphenous vein.

30

61. A method according to any one of claims 57-59, wherein the saphenous vein is the lesser saphenous vein.

62. A method for occluding a first venous vessel, comprising:

- 5 providing within the first venous vessel an elongate occlusion device, the elongate occlusion device traversing at least one junction between the first venous vessel and a second venous vessel.

63. A method according to claim 62, wherein the second venous vessel is a perforator or  
10 communicator vessel.

64. A method according to claim 63, wherein the first venous vessel is a superficial venous vessel.

- 15 65. A method according to claim 64, wherein the first venous vessel is a saphenous vein.

66. An occlusion device useful for occluding a segment of a first venous vessel, the first venous  
20 vessel having a junction with a second venous vessel, the occlusion device comprising an occluder body sufficiently elongate for positioning within the first venous vessel so as to traverse said junction.

- 25 67. An occlusion device according to claim 66, wherein the occluder body comprises a resorbable material.

- 30 68. An occlusion device according to claim 66 or 67, wherein the occluder body comprises a collagenous material.

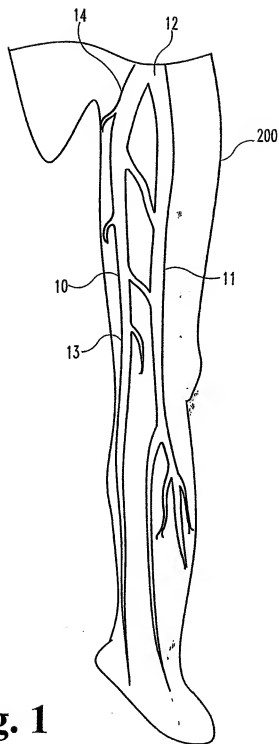


69. An occlusion device according to claim 68, wherein the occluder body comprises an extracellular matrix material.

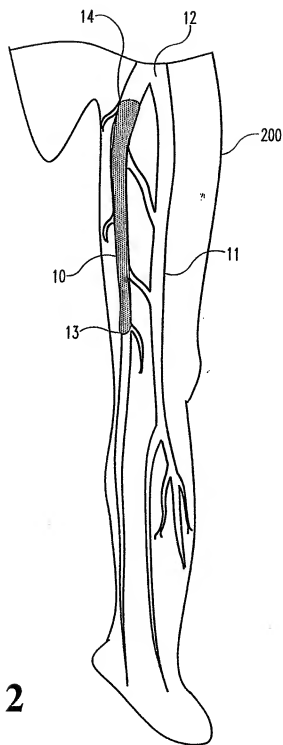
5           70. An occlusion device according to claim 69, wherein the extracellular matrix material comprises submucosa, serosa, pericardium, dura mater, peritoneum, or dermal collagen.

10           71. An occlusion device according to claim 70, wherein the extracellular matrix material comprises submucosa.

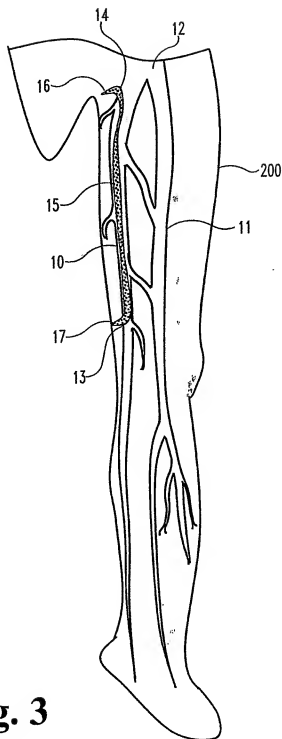
1/40

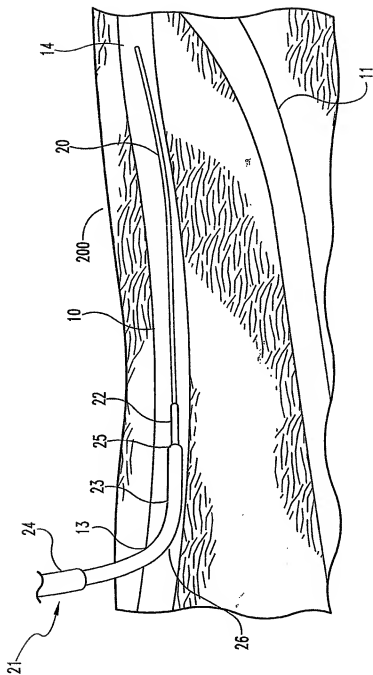
**Fig. 1**

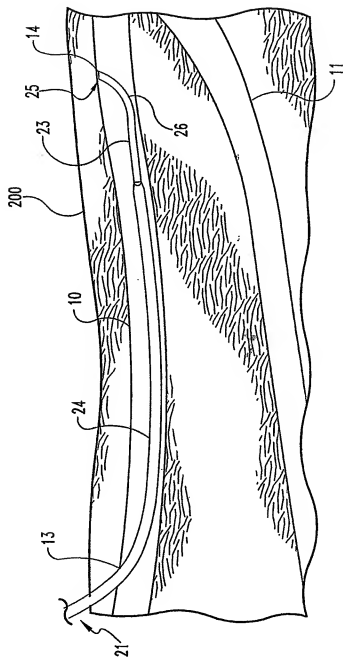
2/40

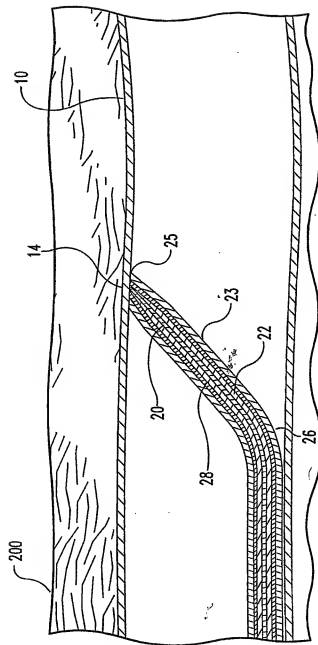
**Fig. 2**

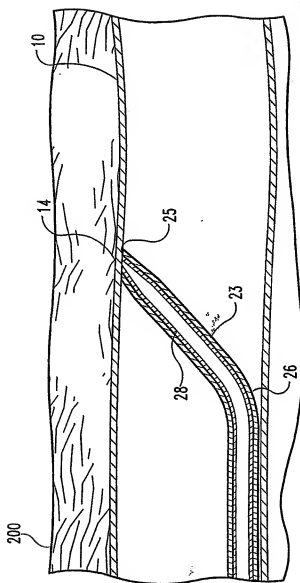
3/40

**Fig. 3**

**Fig. 4**

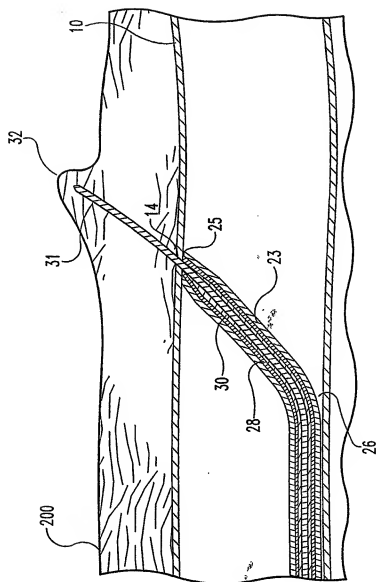
**Fig. 5**

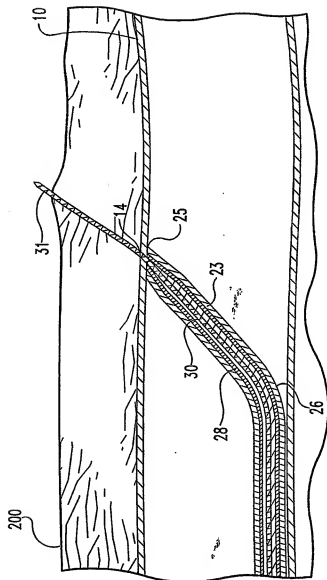
**Fig. 6**



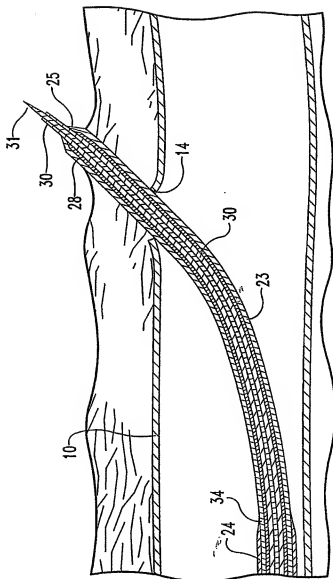
**Fig. 7**

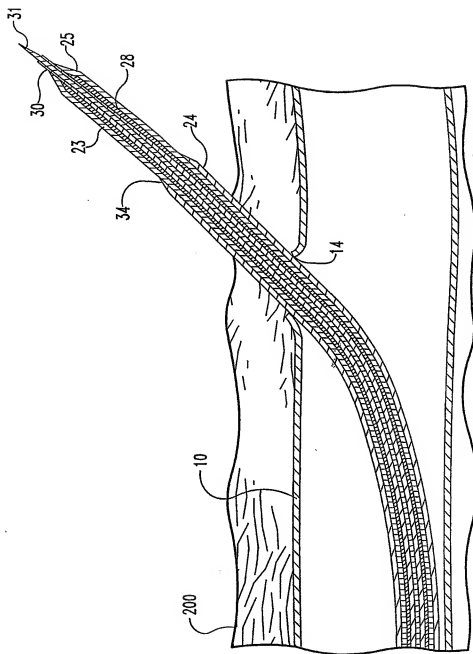






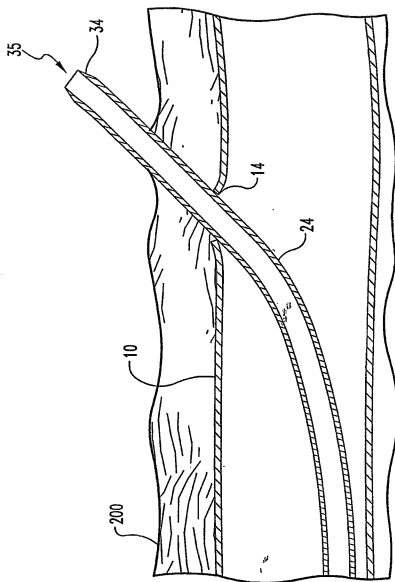
**Fig. 9**

**Fig. 10**

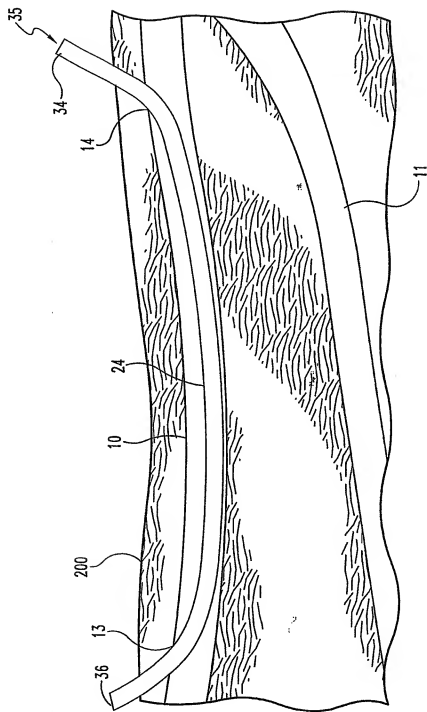


**Fig. 11**

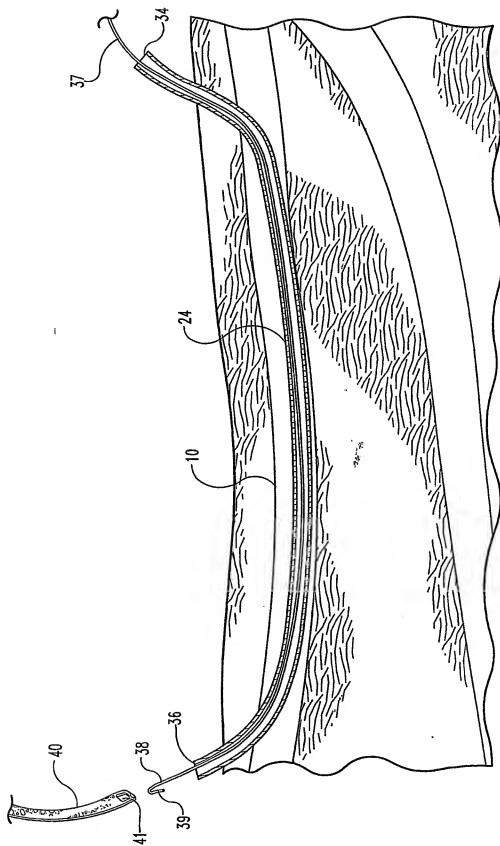
12/40

**Fig. 12**

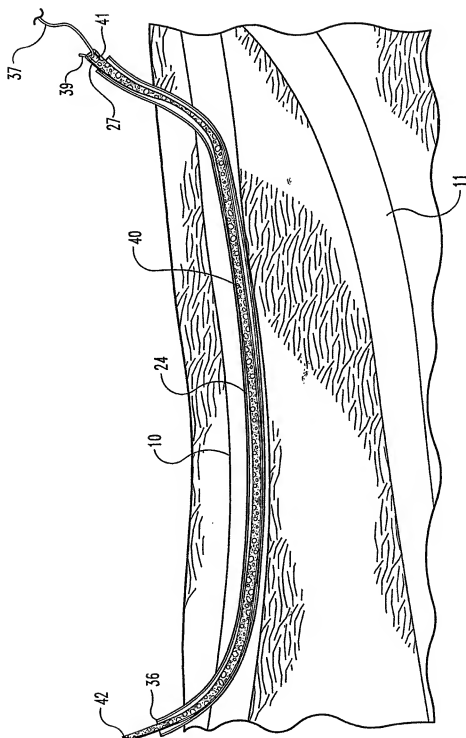
13/40



**Fig. 13**

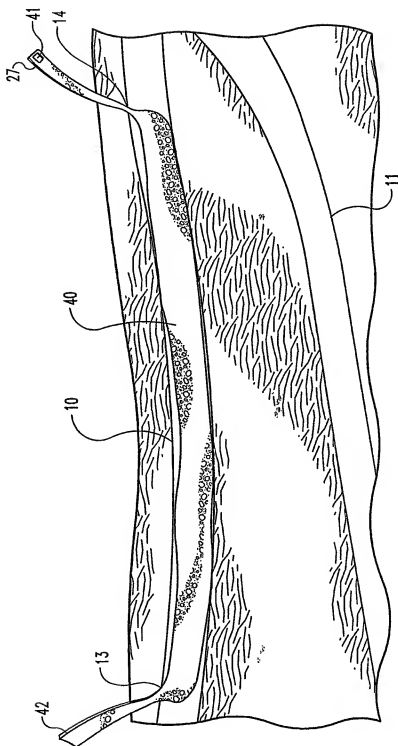
**Fig. 14**

15/40

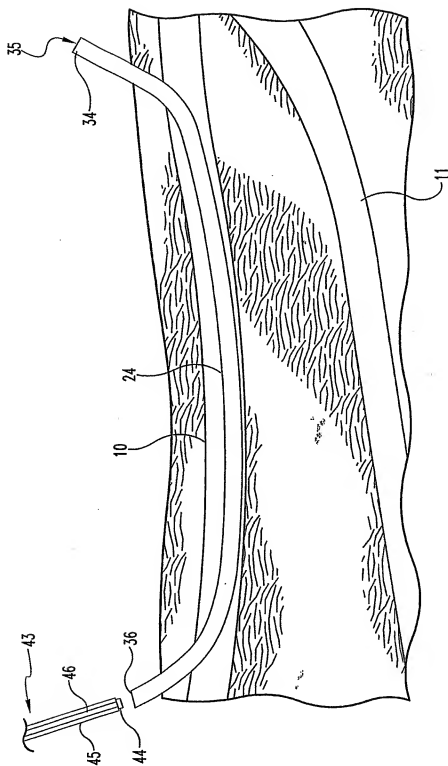
**Fig. 15**

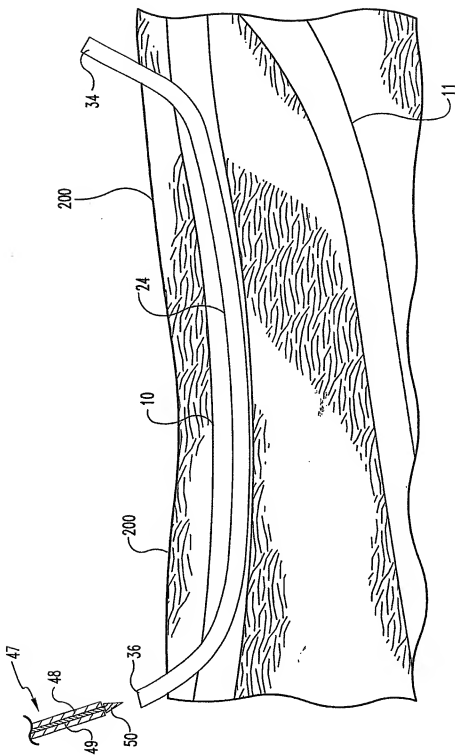


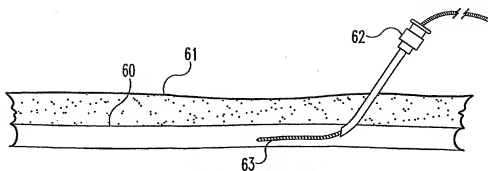
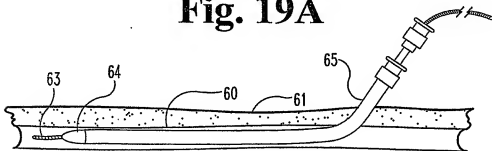
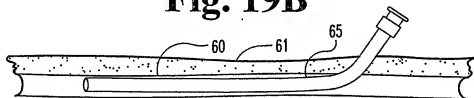
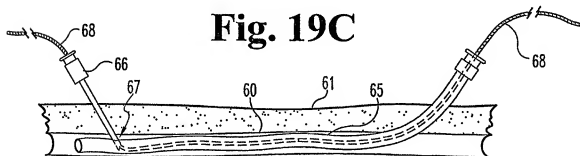
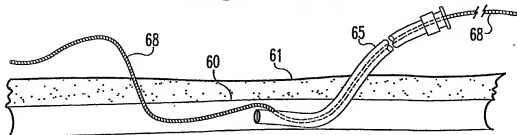
16/40

**Fig. 16**

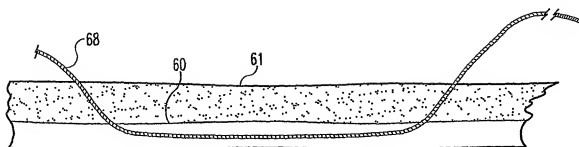
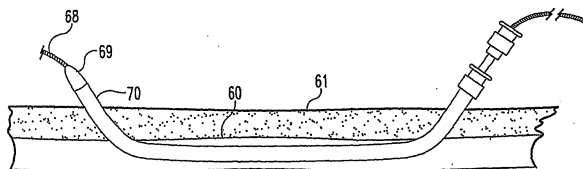
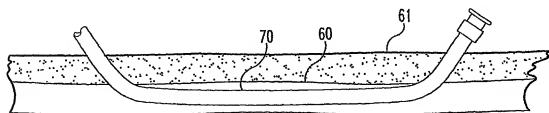
17/40

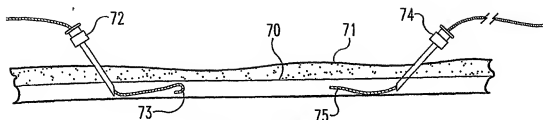
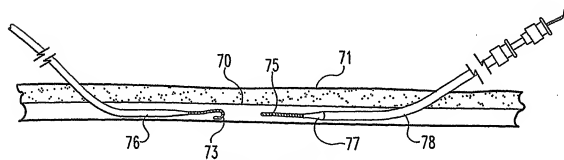
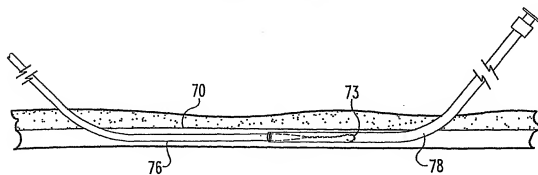
**Fig. 17**

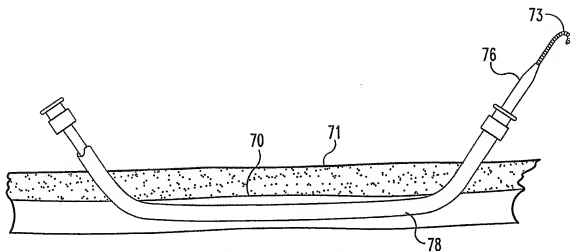
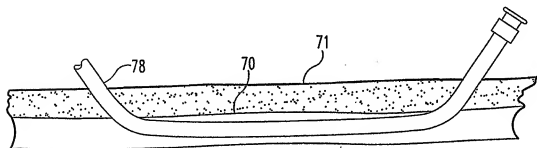
**Fig. 18**

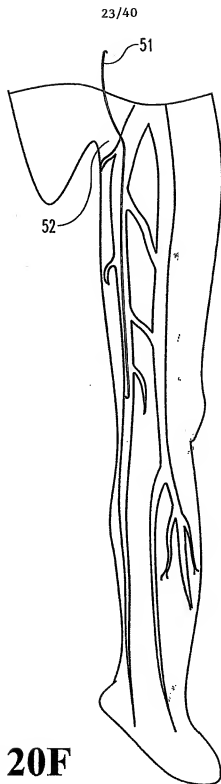
**Fig. 19A****Fig. 19B****Fig. 19C****Fig. 19D****Fig. 19E**

20/40

**Fig. 19F****Fig. 19G****Fig. 19H**

**Fig. 20A****Fig. 20B****Fig. 20C**

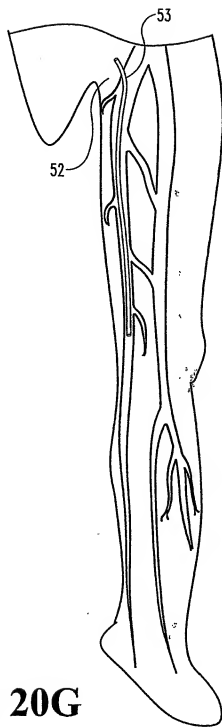
**Fig. 20D****Fig. 20E**



**Fig. 20F**

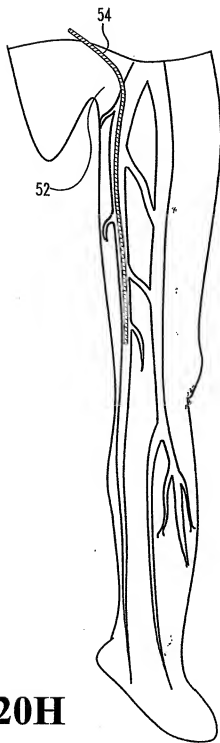


24/40



**Fig. 20G**

25/40



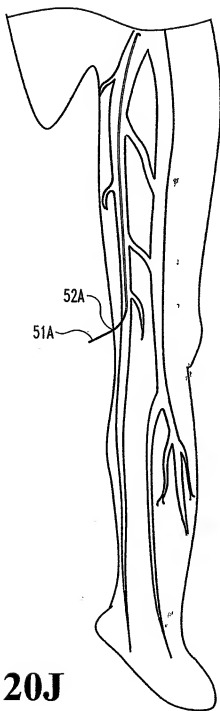
**Fig. 20H**

26/40



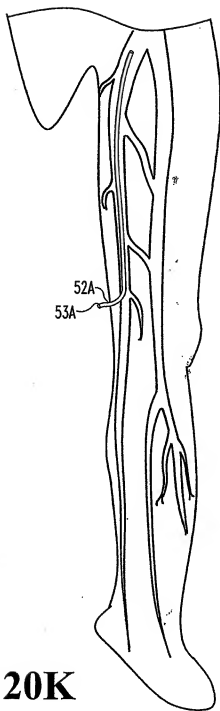
**Fig. 20I**

27/40

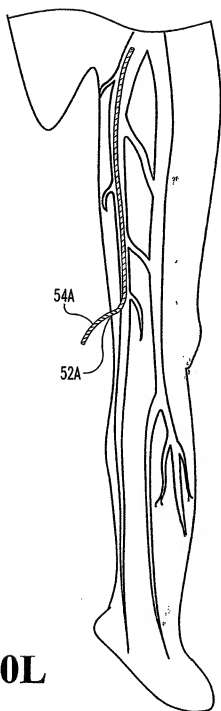


**Fig. 20J**

28/40

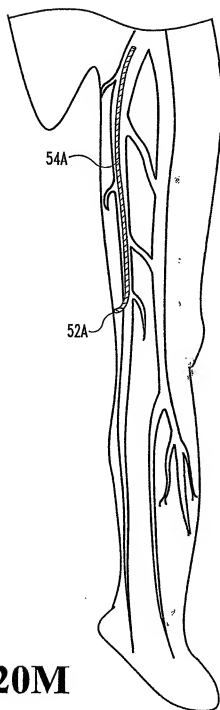


**Fig. 20K**



**Fig. 20L**

30/40



**Fig. 20M**

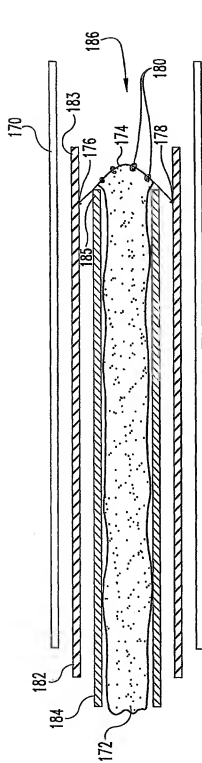


Fig. 20N

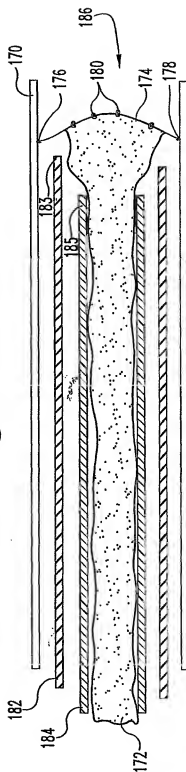
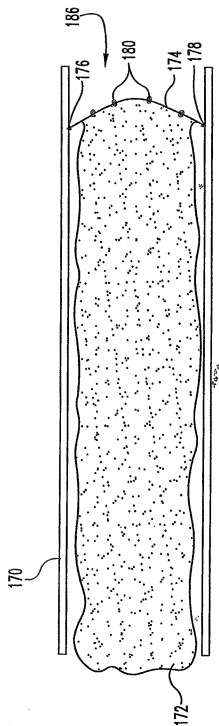


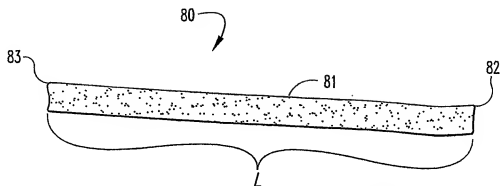
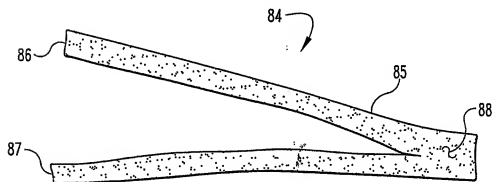
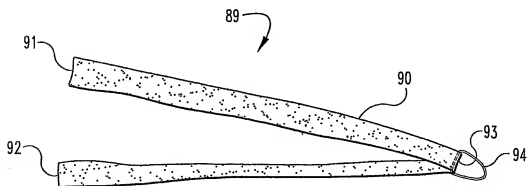
Fig. 200

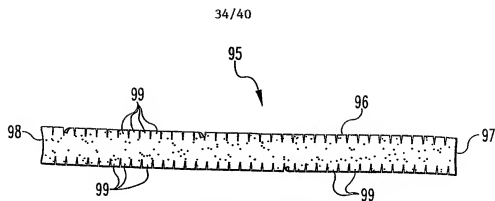
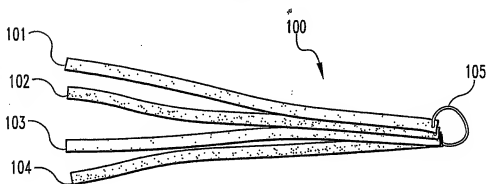
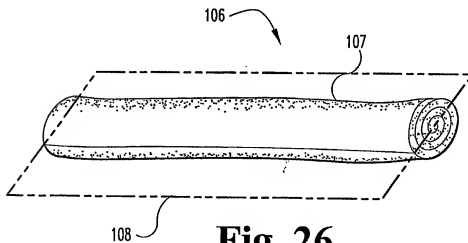


32/40

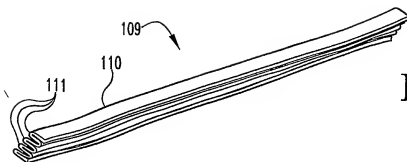
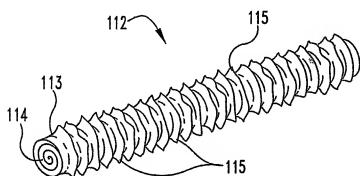
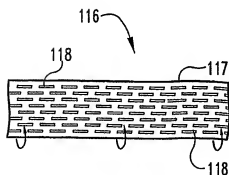
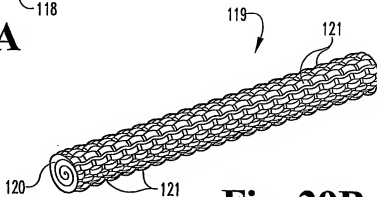
**Fig. 20P**

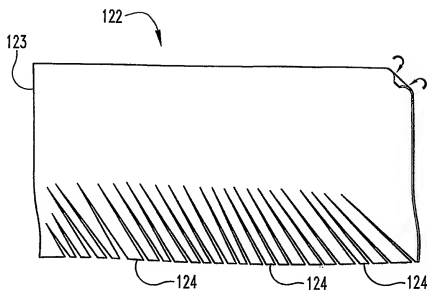
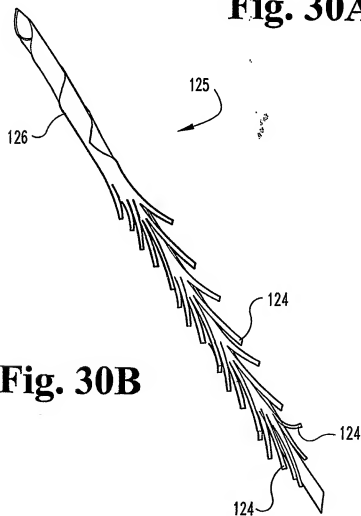
33/40

**Fig. 21****Fig. 22****Fig. 23**

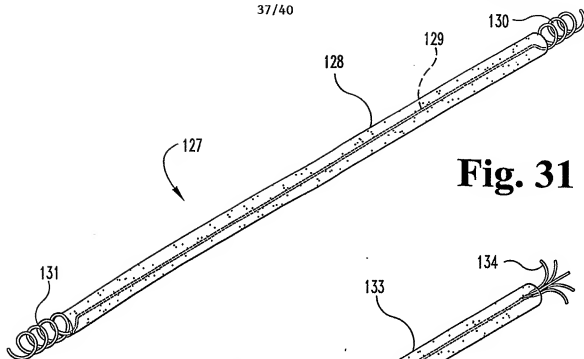
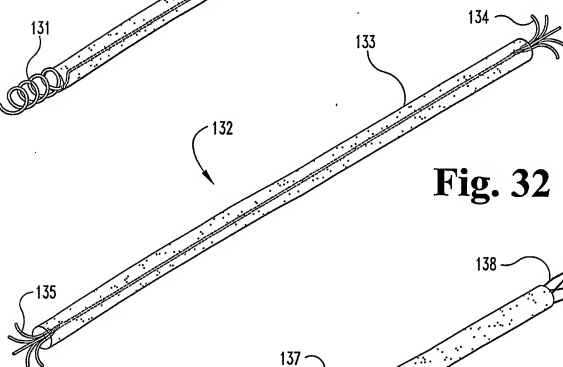
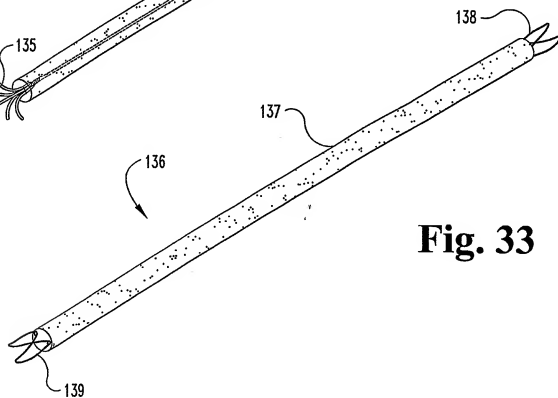
**Fig. 24****Fig. 25****Fig. 26**

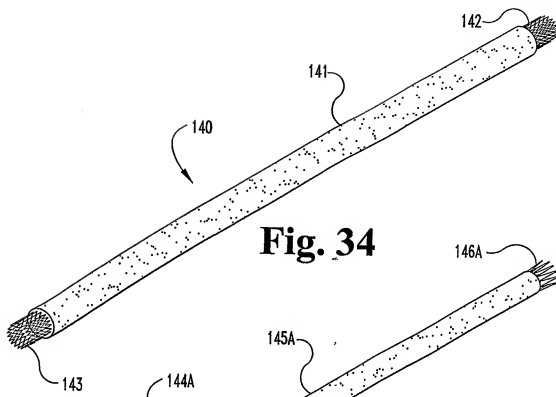
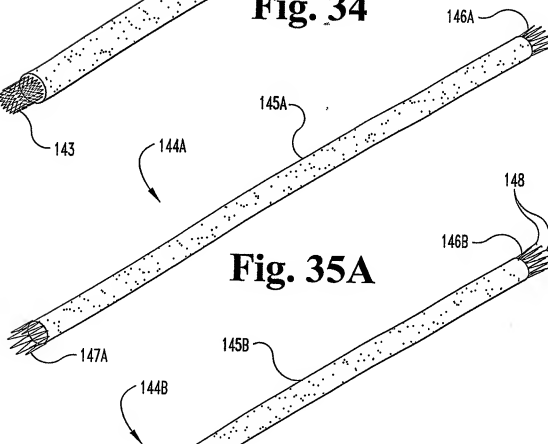
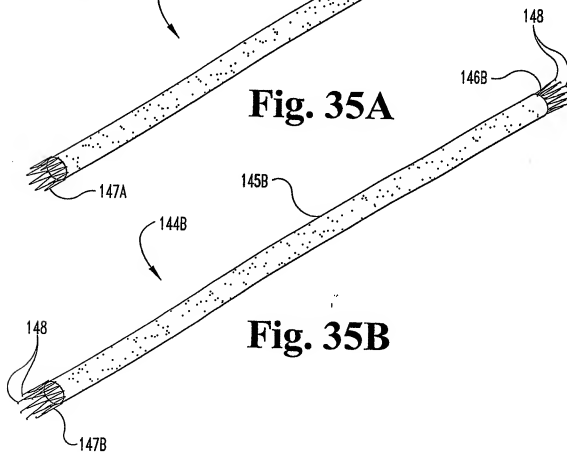
35/40

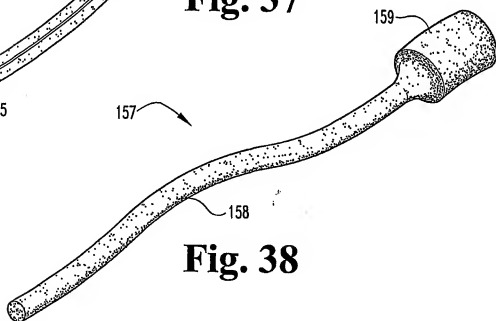
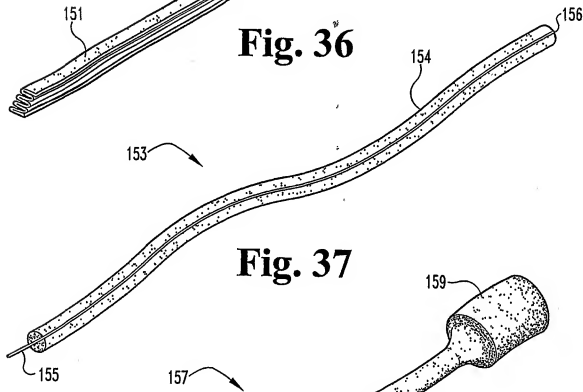
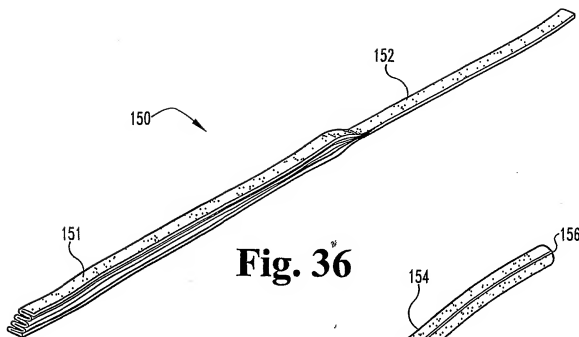
**Fig. 27****Fig. 28****Fig. 29A****Fig. 29B**

**Fig. 30A****Fig. 30B**

37/40

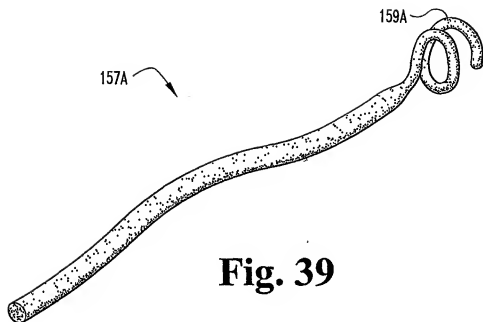
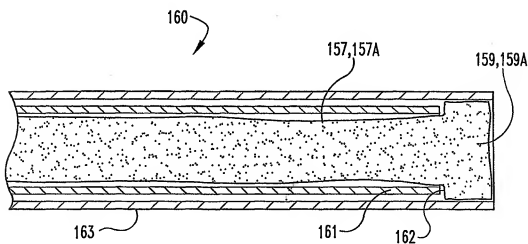
**Fig. 31****Fig. 32****Fig. 33**

**Fig. 34****Fig. 35A****Fig. 35B**





40/40

**Fig. 39****Fig. 40**